REMARKS

Applicant appreciates the detailed examination evidenced by the Official Action mailed September 23, 2004 (hereinafter the "Official Action"). In response, Applicant has amended the specification and several of the dependent claims as suggested by the Examiner to overcome the objections thereto. Applicant submits that the amendments made to the claims are not narrowing, and therefore, a full range of equivalence is still available for these claims.

Applicant also provides herein below a detailed analysis of each of the references cited in the Official Action and reasons for patentability of the pending claims and newly added Claims 29-33. Applicant respectfully submits that the pending and new claims are patentable for at least the reasons discussed herein.

English Language Abstracts of Foreign Patents Documents are Included in the Concurrently Filed IDS

The Official Action noted that the three Foreign Patent Documents: DE3332075, DE4341903, and DE3219558, were not considered as those documents were not in the English language. In response, Applicant has concurrently submitted an IDS including English language abstracts corresponding to the documents listed in the concurrently filed IDS. Applicant respectfully requests consideration of the same.

The specification has been amended to provide antecedent basis for the claim recitations.

The Official Action objected to the specification under 37 C.F.R. 1.75(d)(1) and MPEP § 608.01(o). *Official Action, page 2.* In particular, the Official Action objected to the recitation of a "biocompatible optical translucent layer" in Claim 17. In response, Applicant has amended the paragraph at page 15, lines 20-28, to read that "The circuit may also be coated with a biocompatible optical translucent layer," thereby providing clear antecedent basis for the recitations of Claim 17. Applicant respectfully submits that the amendment does not add new matter to the specification as the claims, as filed, are considered part of the specification.

The Official Action also objected to disclosure in the specification on page 13, lines 33-page 14, line 8, that the transmitted/received data is digitally encoded compared to the recitations that the signal is "digitally encoded via an inductor" in Claim 16. In response, Applicant has amended Claim 16 to remove the recitation of "via the inductor." Applicant submits that the amended specification provides clear antecedent bases for the recitations of Claim 17 and for the amended recitations of Claim 16. Accordingly, Applicant respectfully requests the withdrawal of the objections to the specification.

The Objection to Claim 13 Has Been Overcome by Amendment.

Claim 13 has been objected to over a typographical error therein. In particular, Claim 13 included a recitation of "couple" highlighted by the Official Action. In response, Applicant has amended Claim 13 to change "couple" to "coupled" as suggested by the Examiner. Accordingly, Applicant submits that the objection to Claim 13 has been overcome by amendment and respectfully requests the withdrawal of the same.

The Rejections under § 112 Have Been Overcome by Amendment.

Claims 9 and 16 stand rejected under 35 U.S.C. § 112, second paragraph. *Official Action, page 3.* In particular, the Official Action rejected Claim 9 over the recitation of "a high-powered LED." In response, Applicant has amended Claim 9 to remove the recitation of "high-powered." Applicant respectfully submits that the amendment to Claim 9 overcomes the rejection under § 112, and therefore, the rejection of Claim 9 should be withdrawn. Moreover, Applicant further submits that the amendment does not narrow the scope of Claim 9, and therefore, a full range of equivalents is available to amended dependent Claim 9.

Claim 16 is objected to over the recitation of "the signal is digitally encoded via the inductor." In response, Applicant has amended Claim 16 to remove the recitation of "via the inductor." Applicant respectfully submits that the amendment to Claim 16 overcomes the rejection under § 112, and therefore, the rejection of Claim 16 should be withdrawn. Moreover, Applicant respectfully submits that the amendment to Claim 16 does not narrow the scope thereof and, therefore, a full range of equivalents is available to amended dependent Claim 16.

Independent Claim 8 is Patentable Over The Cited References.

Claims 8-11 stand rejected under 35 U.S.C. § 102 over U.S. Patent No. 5,833,603 to Kovacs et al. ("Kovacs"), Claims 8 and 14-17 stand rejected under § 102 over U.S. Patent No. 6,551,838 to Santini, Jr. et al. ("Santini"), and Claims 8-13 stand rejected under § 102 over U.S. Patent No. 6,343,227 to Crowley ("Crowley"). *Official Action, pages 4-6.* Applicant respectfully submits that independent Claim 8 is patentable over Kovacs, Santini, and Crowley for at least the reasons discussed herein.

Under 35 U.S.C. § 102, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 (quoting *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)). "Anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention." *Apple Computer Inc. v. Articulate Sys. Inc.*, 57 U.S.P.Q.2d 1057, 1061 (Fed. Cir. 2000). "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" M.P.E.P. § 2112 (citations omitted).

A finding of anticipation further requires that there must be no difference between the claimed invention and the disclosure of the cited reference as viewed by one of ordinary skill in the art. *See Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). In particular, the Court of Appeals for the Federal Circuit held that a finding of anticipation requires absolute identity for each and every element set forth in the claimed invention. *See Trintec Indus. Inc. v. Top-U.S.A. Corp.*, 63 U.S.P.Q.2d 1597 (Fed. Cir. 2002). Additionally, the cited prior art reference must be enabling, thereby placing the allegedly disclosed matter in the possession of the public. *In re Brown* , 329 F.2d 1006, 1011, 141 U.S.P.Q. 245, 249

(C.C.P.A. 1964). Thus, the prior art reference must adequately describe the claimed invention so that a person of ordinary skill in the art could make and use the invention.

Applicant respectfully submits that Kovacs does not disclose the recitations of Claim 8 with the specificity required of a rejection under section 102:

> an optical radiation source configured for *in vivo* use that emits first optical radiation;
>
> **an optical radiation detector configured for *in vivo* use that detects second optical radiation emitted by excited labeled binding molecules**; and
>
> a processor circuit, coupled to the optical radiation source and the optical radiation detector, that controls the emission of the first optical radiation and that receives an intensity signal associated with the intensity of the second optical radiation and **transmits a signal associated with the intensity of the second optical radiation to an *ex vivo* system**.

Contrary to assertions in the Official Action, Kovacs does not disclose, for example, an optical radiation detector...that detects second optical radiation **emitted by excited labeled binding molecules** and a processor circuit...that **transmits a signal associated with the intensity of the second optical radiation to an *ex vivo* system**.

As understood by Applicant, Kovacs focuses on the use of dyes as chemical sensors whose optical properties change in response to a physical property of the environment into which the dyes are introduced:

> Biosensing transponders utilizing photosensors can also include one or more optical emitters for illuminating the implant site with specific wavelengths. For example, red and infrared light emitting diodes (LEDs) can be used for alternately illuminating the implant site to facilitate optical oximetry. **Similarly, optical emitters can be used to illuminate chemical sensitive dyes so that the photosensor can detect a change in an optical property of the dyes to thereby detect a physical property of the external environment.** The photosensor can be used with optical filters for shielding the photosensor from particular wavelengths, or the photosensor can be embodied in an integrated spectrophotometer. *Kovacs, col. 5, lines 15-27(emphasis added).*

As understood by Applicant, the sensing device discussed in Kovacs uses a first dye 56 that is in contact with an external environment and a second dye 58 which is not in contact with the external environment. In operation, the first and second dyes are illuminated and the emissions therefrom are observed and compared. In particular, it appears that the optical properties of the first dye 56 may change in response to the

external environment so that optical radiation emitted therefrom may be a different wavelength compared to the optical radiation emitted by the second dye 58. As further understood by Applicant, the wavelengths of the first and second dyes can be compared to determine the shift caused by the external environment. *See, for example, column 10, lines 3-65, Kovacs.*

In view of the nature of Kovacs as illustrated above, Applicant respectfully submits that the fact that the devices discussed in Kovacs are configured to work with dyes (and the changes the dyes undergo) does not disclose an "optical radiation detector that is configured to detect second optical radiation emitted by **excited labeled-binding molecules**" for the purposes of § 102. In other words, the dye-based sensors in Kovacs do not necessarily disclose (or inherently disclose) the specific recitation of Claim 8, which focuses on the specific configuration "to detect second optical radiation emitted by **excited labeled-binding molecules**."

Moreover, Kovacs does not disclose transmitting "a signal associated with the intensity of the second optical radiation to an *ex vivo* system" as Kovacs appears to discuss transmitting a change in the optical properties to another system, not transmitting a signal associated with the intensity of the second optical radiation to an *ex vivo* system as recited in independent Claim 8. For example, in summarizing the sensors discussed therein Kovacs states that:

> Thus, the biosensing transponder of the present invention can be configured to detect almost any physical property or parameter value related to an organism, and wirelessly transmit this information to a remote reader in a simple, inexpensive, and non-invasive fashion. The detected physical property may directly relate to a patient's tissue or cells, or may instead be related to any other implant within the patient. Additionally, the biosensing transponder of the present invention can be utilized with other medical devices, including flexible catheters, for facilitating various observations and procedures. *Kovacs, col. 5, lines 28-38.*

As demonstrated by the above-cited passage of Kovacs, the discussion therein is too generic to statisfy the specific requirement of a rejection under section 102 (*e.g.*, the biosensing transponder of the present invention can be configured to detect almost any physical property or parameter value related to an organism is too general to disclose the specific recitations discussed above). Accordingly, Applicant respectfully submits that independent Claim 8 is

patentable over Kovacs for at least the reasons discussed above. Furthermore, dependent Claims 9-17 are patentable at least per the patentability of independent Claim 8.

With respect to the rejection based on Santini, Applicant respectfully submits that Santini does not disclose, at least, "an optical radiation detector configured for *in vivo* use that detects second optical radiation emitted by **excited labeled-binding molecules**" and a processor circuit...that transmits "**a signal associated with the intensity the second optical radiation to an *ex vivo* system**."

Santini discusses an optical sensing device:

> In another embodiment, illustrated in FIGS. 3A-B, a miniature optical fiber **24** is placed in or near a reservoir **14** disposed in substrate portions **12a** and **12b** of microchip device **10**, having semi-permeable barrier layer **20** and backing plate **16**. Reservoir **14** contains one or more substances "X" that interact with one or more molecular or cellular component of interest "A", present in the environment around the microchip device (outside the reservoir). As shown in FIG. **3B**, the substance X inside the reservoir **14** is exposed by the partial removal of an initially present barrier layer **18** to the environment containing the molecule or cellular component of interest "A". Then an optical property of the substance inside reservoir **14** changes (X→X') and is sensed via optical fiber **24**. For example, the optical fiber **24** may be used to expose the contents of the reservoir **14** to a light source, possibly of a single wavelength. The optical fiber **24** also can have the ability to detect and measure changes in fluorescence, or some other optical phenomenon. *Santini col. 18, lines 7-24.*

As demonstrated by the above-cited passage in Santini, the optical sensing device discussed therein is not configured to detect optical radiation emitted by "**excited labeled-binding molecules**." Furthermore, there is no disclosure in Santini of a processor circuit that transmits a signal associated with the intensity of the second optical radiation to an *ex vivo* system. Accordingly, applicant respectfully submits that independent Claim 8 is also patentable over Santini for at least the above reasons. Furthermore, Claims 14-17 are patentable over Santini at least per the patentability of independent Claim 8.

With regard to the rejection under § 102 based on Crowley, it also appears that Crowley does not disclose, at least, an optical radiation detector configured for *in vivo* use that detects "**second optical radiation admitted by excited labeled-binding molecules**" and ...a processor circuit that transmits "**a signal associated with the**

intensity of the second optical radiation to an *ex vivo* system" as recited in independent Claim 8.

The entire disclosure of Crowley appears to discuss an interventional type system (such as that that would be used via a catheter or a trocar) that would be inserted for the purposes of measurement and then removed so that the patient could then be released. In contrast to the nature of Crowley, Applicant's disclosure discusses at length the chronically implantable nature of embodiments according to the invention. For example, Applicant's disclosure states:

> **FIG. 1** is a schematic illustration of embodiments according to the present invention that can be used to determine antigen levels of *in vivo* tumor tissue **110**. The tumor tissue **110** may be characterized by a type of tumor specific antigen (TSA) **195** located at the surface **100** of the tumor tissue **110**. For example, a TSA **195** may be found on the surface of cell tissue **110**. In general, suitable biomolecules (*i.e.*, TSAs) indicative of tumor cell proliferation are essentially independent of many of the biological, physiological, and/or environmental properties that are found in solid tumors. Although only a single surface of tissue **110** is shown, it will be understood that embodiments according to the present invention may be utilized to detect biomolecule concentrations for a plurality of tissue **110**.
>
> The phase of the tumor tissue **110** may be detected based on a concentration level of the TSA **195** at the surface **100**. For example, a "growth" phase of the tumor may be characterized by relatively high concentrations of the TSA **195** and a "remission" phase may be characterized by relatively low concentrations of TSA **195**. *Application, page 8, lines 1-14*

Applicant's disclosure goes on to state that:

> The *in vivo* system can transmit data to the *ex vivo* system. For example, the *in vivo* system can transmit data associated with the intensity of the optical radiation **520**. The *in vivo* system can transmit other data to the *ex vivo* system. Accordingly, the *in vivo* system can be implanted for *in vivo* use whereby the *ex vivo* system can control operations of the *in vivo* system including receiving data from the *in vivo* system without an associated invasive procedure. *Application, page 14, lines 9-14.*

And further, that: "**[t]he lifetime of the implant may be as long as six months or even more in some cases**." *Application, page 15, lines 18-19 (emphasis added).* As demonstrated by the above-cited passages from Applicant's disclosure, the cited embodiments according to the invention focus on the chronically implantable nature of the claimed circuits/apparatus and, moreover, the transmission of data *in vivo* to an *ex vivo* system

throughout the life of the chronically implanted (*e.g.*, 6 months) circuit or apparatus. Accordingly, the terms recited in the present claims (such as *in vivo/ex vivo* and implantable) refer to, for example, the types of embodiments cited above.

In contrast, Crowley states that:

> Referring to Fig. **3**, the spectrometer module **41** of Fig. **2**a is disposed at the distal end of an interventional device **70**. In the disclosed embodiment, the module **41** is attached to the distal end of a shaft **71**, and the shaft **71** houses signal wires **9**, **10**, and **13**. The shaft **71** terminates with a small connector **73** at the proximal end. The connector **73** may have one or more contacts arranged to permit electrical, optical, and mechanical connection to a mating connector. The shaft **71** also has a slidable stop **75** that may be prepositioned to allow control of the depth of placement within the body. The stop may be a collar with a collet ring **77** that tightens when twisted to provide a positive stop. The shaft **71** may comprise a tube, such as stainless steel hypo tube, superelastic (nitinol) tube, or the like. The advantage of such shafts is that they are relatively rigid and allow insertion into partly occluded passages. Very small shafts may be made with metal tubes. Shafts having outside diameters of about 0.005 inches may be provided, although in most instances, larger shafts with diameters of about 0.08 inches or larger are adequate. *Crowley pg. 5, line50 to pg. 6, line 2.*

As demonstrated by the above-cited passage of Crowley, the entire discussion therein appears to focus on short-term interventional devices, such as the catheters shown in Fig. 4, which appear to be inserted for a relatively short period of time for the purposes of instantaneous measurements and subsequent removal. Accordingly, Crowley does not disclose, for example, a processor circuit that "transmits a signal associated with the intensity of a second optical radiation to an *ex vivo* system" as described in the specification. Therefore, independent Claim 8 is patentable over Crowley for at least these reasons. Further, dependent Claims 9-13 are patentable over Crowley at least per the patentability of independent Claim 8.

The new claims are also patentable.

Applicant has added new Claims 29-33, which are also patentable over the cited references. For example, new claim 29 recites in-part:

> first and second optical radiation at respective first and second wavelengths **selected to promote transmission of the first and second optical**

radiation through a bio-fouling tissue on the optical radiation source and the optical radiation detector,

which is not disclosed by the cited references. For example, Santini discusses using a bio-compatible layer to cover the sensor, which as understood by Applicant is to prevent the deposition of a bio-fouling tissue. Accordingly, Santini appears to avoid having to transmit through a bio-fouling tissue.

New Claim 30 recites in-part: "a chronically implantable configured for *in vivo* implantation for at least six months," which is not disclosed by the cited references. For example, as discussed above Crowley focuses on short-term interventional devices (such as catheters).

New Claim 32 recites in-part that "the processor circuit is configured to control the release of labeled binding molecules for excitation by the first optical radiation." None of the cited references disclose, for example, the controlled release of labeled binding molecules.

New Claim 33 recites in-part that "the processor circuit is configured to enable the optical radiation detector a selectable time interval after enabling the optical radiation source." None of the cited references disclose, for example, the controlled release of labeled binding molecules.

CONCLUSION

Applicant has amended several of the claims and the specification in response to the issues raised in the Official Action. Applicant has also shown herein that the cited references do not disclose the recitations of the pending and new claims. Accordingly, Applicant respectfully requests withdrawal of the rejections and the allowance of all claims in due course. If any informal issues arise, the Examiner is invited to contact the undersigned by telephone.

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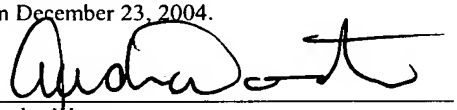

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